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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/653,325	09/02/2003	Allan H. Graff	C75128-1	2971

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/653,325	GRAFF ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, request for continued examination under 37 CFR 1.114, amendment and remarks, filed 6/30/2008. Claims 3, 6, 18 and 32 are canceled. New claims 35-53 are added. Claims 1, 2, 4, 5, 7-15, 17, 19-31 and 34 are canceled. New claims 35-53.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/30/08 has been entered.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 35-45, 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muhammad (US 5,167,964) in view of Santus (US 6,280,761) and further in view of Rapp et al. (US 6,180,143 B1) or Burnick et al. (US 2003/0017202 A1).

Muhammad discloses flavored lozenges formulation and that lozenge bases are generally hard boiled candy lozenges or compressed tablet lozenges (column 8, lines 53-58). The disclosure of lozenges meets the limitation of claims 35-51. Muhammad specifically discloses that hard-boiled candy lozenges are amorphous or glassy (column 8, lines 59-64) meeting the limitation of claim 35. Muhammad's formulation comprises medicaments and nicotine is specifically mentioned (column 4, lines 47 and 48) with the nicotine meeting the limitation of claims 1c) and claims 35 and 46. The formulation comprises bulking agents, flavoring agents sweetening agents and buffers (column 8, lines 31-33; column 2, lines 60-65; column 10, lines 64-68); the buffering agents and flavoring agents meet the limitations of claims 47, 50 and 51 and with regards to claim 51, "non-pharmacological component" is a flavor agent according as gleaned from the instant specification at paragraph [0039]. The formulation may comprise 95%

of a mixture sugar alcohols of sorbitol and mannitol in a ratio from about 9.5:0.5 to about 7.5:2.5 (column 9, lines 12-17) meeting the limitations of the claim 35 and the 95% sugar alcohol of Muhammad meets the limitations of claims 50. Claim 39 recites the properties of the dosage form of claim 35, and since a composition cannot be separated from its properties and because Muhammad discloses the dosage of claim 35, it flows that the dosage form of Muhammad possesses the properties recited in claim 39. Sufficient amount of gelling gum that provides oral dissolution rate as recited in claim 35 is any amount deemed sufficient by the artisan and Muhammad meets that limitation. For example, Muhammad specifically discloses that the effective amount of the medicament may vary depending on the recommended therapeutic dosage or the dose permitted for the particular medicament and that such dosages are known to the skilled artisan in the medical arts (column 5, lines 10-16). Furthermore, the formulation/dosage of Muhammad contains suspending or thickening agents such as carrageenans, xanthan gums, gelatin and celluloses, with the preferred amount of the thickener present at from about 1% to about 15% and a point within this range anticipates the recited amounts of gum in claims 40-42 and the presence of xanthan gum in the dosage of Muhammad meets the limitations of claims 37, 38 and 40-42. Claim 35 is product by process claim; Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps and "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777

F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The nicotine is contained in the glassy matrix.

Muhammad does not teach incorporating specific amount of the nicotine in the dosage form as required by claim 35. But Santus prepares lozenges containing fairly low doses of nicotine in preferred amounts of 0.5 to 5 mg, and in most preferred amounts of 0.5 to 2 mg (column 6, lines 3-9).

Muhammad in view of Santus discloses the dosage of claim 35. The combined reference of Muhammad and Santus does not disclose the mixed sugar alcohols that is ISOMALT recited in the claims, specifically claims 35, 43-45. However, Rapp discloses nicotine formulation that contains a sweetening agent mixture of 1.6-GPS, 1.1-GPS and 1.1-GPM (abstract; column 4, lines 38-67; claim 9), the sweetener mixture is comprised of 10-50% by weight of 1,6-GPS, 20% by weight of 1,1-GPS and 30-70% by weight of 1,1-GPM (column 2, lines 46-60; column 4, line 43-67; claims 2-5 and 14). The sweetener in Rapp and in the amounts disclosed renders obvious the sweetener of claims 43-45. Example 3 uses ISOMALT, a sweetener that is a mixture of 1, 6-GPS and 1,1-GPM; the ISOMALT is the sugar alcohol present in claim 35 and 43-45. Also, Burnick discloses formulation that contains nicotine, ISOMALT and xanthan gum (abstract; paragraph [0012]; paragraph [0015].

Therefore taking the teachings of the references together, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that incorporation of the mixed sugar alcohols known in the art to be formulated with nicotine according to Rapp or Burnick, using the doses of nicotine suggested by Santus, would be

expectation to impart low hygroscopy to the nicotine lozenge. ISOMALT is a mixture of 1,6-GPS and 1,1-GPM.

5. Claims 35, 46, 52 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muhammad et al. (US 5,167,964) in view of Santus (US 6,280,761) and further in view of Rapp et al. (US 6,180,143 B1) or Burnick et al. (US 2003/0017202 A1).

Muhammad is described above for disclosing nicotine dosage form in a glassy matrix. Many types of nicotine are known in the art as evidenced by the disclosure of Santus that nicotine polacriflex, a nicotine gum is a commercially available source of nicotine for replacement therapy (column 2, lines 8-11), meeting claim 35. Muhammad does not disclose a method of reducing nicotine craving. Santus describes a method for smoking cessation therapy, the method, comprising administering nicotine lozenge to a person in need thereof to satisfy transient craving (abstract; column 4, lines 19-28) and further discloses that lozenges containing fairly low doses of nicotine in preferred amounts of 0.5 to 5 mg, and in most preferred amounts of 0.5 to 2 mg are administered (column 6, lines 3-9), thus meeting claims 35, 52 and 53. Administration of the dosage form of Muhammad as modified with Santus would inherently produce blood plasma nicotine levels of nicotine. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use modified dosage form of Muhammad in which between 0.5 and 5 mg nicotine is used according to Santus with the expectation that the low dose of the nicotine in the lozenges would satisfy transient craving, which would lead to smoking cessation according to Santus.

6. Claims 35, 47, 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muhammad et al. (US 5,167,964) in view of Santus (US 6,280,761) and further in view of Rapp et al. (US 6,180,143 B1) or Burnick et al. (US 2003/0017202 A1).

7. Muhammad is discussed above. Muhammad in view of Santus as it regards the amount of the nicotine is also described above. While Muhammad discloses the use of phosphate buffers (column 2, line 65 and column 10, lines 64-66), there is no disclosure for specific phosphate buffers. But, the buffers recited in claim 48 and the buffers of claim 49 are common phosphate and carbonate buffers that can be used interchangeably to maintain the pH of the product at the desired pH level. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use any of the known phosphate and carbonate buffers and expect the formulation to be buffered at the desired pH.

Response to Arguments

8. Applicant's arguments filed 6/30/08 as the arguments relate to the new rejections have been fully considered but they are not persuasive.

9. Applicant argues that Mohammad does not teach the claimed Lozenges prepared by the method recited in claim 35. The examiner disagrees because product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps and "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the

10. Applicant argues that Santus does not teach the current method or preparing the lozenges according to new claim 35. The examiner disagrees with applicant's premise for traversing the Santus reference. Claim 35 and those dependent therefrom are product by process claims. And, Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps and "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Santus is relied upon for teaching the amounts of nicotine recited in the claims and not on how the lozenges are made.

11. Applicant further argues that Rapp and Burnick do not relate to non-hygroscopic, glassy formulation so that combination of either or both of the references with Muhammad would not result in the present invention; that although, a product by process claims is not limited by the steps in the method, in the present case, the steps lead to the claimed glassy lozenges that is amorphous. The examiner disagrees. Muhammad specifically discloses that hard-boiled candy lozenges are amorphous or glassy (column 8, lines 59-64) meeting the limitation of claim 35. Thus, Rapp and Burnick do not have to teach glassy or amorphous matrix since the primary reference teaches that. Rapp and Burnick are relied upon, each, for teaching combination of ISOMALT with nicotine.

12. On the whole, applicant appears to be arguing against the references individually. But one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Muhammad in view of Santus and further in view of Rapp or Burnick teaches all the elements of the respective claims in the rejections because i) Santus provides a teaching of nicotine dosages that contain 0.5 to 5 mg nicotine and also teaches various of types of nicotine as described in the rejection, ii) Rapp and Burnick are relied upon for using sugar alcohols such as ISOMALT, mixtures of 1,6-GPS and 1,1-GPM with nicotine as described in the rejections. The net result is that the combination of Muhammad with Santus, and Muhammad with Santus and further with Rapp or Burnick teaches all the limitations of the claims.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Blessing M. Fubara/
Examiner, Art Unit 1618